85-838(1)

Supreme Court, U.S.
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NO. 85-

IN THE
SUPREME COURT OF THE UNITED STATES

PAULETTE KARAM, Special Administratix
of the Estate of George L. Karam,
Deceased,

Plaintiff-Petitioner

v.

UNITED STATES OF AMERICA,

Defendant-Respondent

PETITION FOR A WRIT OF CERTIORARI
TO THE UNITED STATES COURT OF APPEALS
FOR THE SEVENTH CIRCUIT
No. 84-1311

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October 29, 1985

QUESTION PRESENTED

Whether Plaintiff-Petitioner was not disabled as a result of a Swine Flu shot, is consistent with decisions of other Courts in this Circuit and other Circuits?

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REFERENCES OF OFFICIAL REPORTS

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Karam v. United States of America, United States Court Of Appeals For The Seventh Circuit, No. 84-1311

JURISDICTIONAL STATEMENT

Jurisdiction for this appeal is invoked pursuant to Title 28 U.S.C. Section 1346(b) and § 267 et seq. and the National Swine Influenza Immunization Program of 1976 (Swine Flu Act), 42 U.S.C. §§ 247(b), et seq. Following a mandatory bench trial, Judgment was entered in favor of Defendant on February 9, 1984. On appeal to the United States Court of Appeals for the Seventh Circuit, the court affirmed, on July 31, 1985. A Petition for Rehearing was not filed.

APPLICABLE LAW

The applicable statutes are 42 U.S.C. §§ 247(b) et seq.

STATEMENT OF THE CASE

This was an action in United States District Court for the Northern District of Illinois, Eastern Division for personal injury, wrongful death, and damages under the National Swine Flu Immunization Program Act of 1976, 42 U.S.C. Section 2476, and the Federal Tort Claims Act, 28 U.S.C. Section 1346(b), et seq. After a mandatory bench trial, the judge found for the defendant, rejecting the treating physician's diagnosis and improperly evaluating the standards for determining Guillain-Barre Syndrome.

STATEMENT OF THE ISSUES PRESENTED FOR REVIEW

I. WHETHER THE COURT'S FAILURE TO FIND THAT GEORGE KARAM HAD GUILLAIN-BARRE SYNDROME (GBS) WAS CLEARLY ERRONEOUS.

II. GEORGE KARAM'S POST-VACCINAL CONDITION FALLS UNDER THE UMBRELLA OF (GBS), THUS, EQUITY FINDS THE GOVERNMENT LIABLE FOR HIS SUFFERING.

STATEMENT OF FACTS

GEORGE L. KARAM, on December 3, 1976 received a swine flu shot. After the vaccination, he was unable to walk without a cane, never worked again or drove his car; he did absolutely nothing. (R. 6)

Elias Stambolis, George's family physician, administered the acknowledged injurious vaccination on December 3, 1976, in his office. At the time George received the vaccination he was in "very good" health. (R.30) But, four to five days later George went back to Doctor Stambolis' office complaining of leg problems. Doctor Stambolis examined him neurologically and found that George did not have any reflexes. (R. 30) While in the hospital George was examined by Dr. Henry, a neurosurgeon, and Dr. Yap, a neurologist. After consultation with the two specialist physicians, Doctor

Stambolis diagnosed George as suffering from permanent Guillain-Barre Syndrome[1] (hereinafter referred to as "GBS"). (R. 32)

Dr. Stambolis determined that after December 3, 1976, George had peripheral nerve problems in his legs and that he had diminished tendon reflexes. (R. 33) Although Dr. Stambolis' records do not show an entry of diminished reflexes until March 28, 1977, he testified that when he examined George on December 7, 1976, the leg reflexes were diminished, but he failed to record it. (R. 58,59,60)

Dr. Nilges, a neurologist, testified:

> "Mr. Karam was walking and able to function as an insurance agent up to the time he had the swine flu vaccination shot on December 3rd. I believe it was four days following that he developed weakness. He was almost unable to walk. So the rapid progression of weakness following a recognized cause such as vaccination holds. Several examinersexamined him, one of whom found absent or reduced reflexes in the arms, positive extensor-plantar or Babinski

> response in the left foot, question of positive one in the right; also found that he could not stand, he tended to fall when he was placed in a standing position, all these indicated the rapid onset of muscle weakness following a recognized cause, in a man previously able to navigate and walk satisfactorily." (R. 111, 112)

He found:

> That a weak, wide-based, in other words, he planted his feet far apart in order to maintain himself without falling -- a weak, wide-based walking or gait, an absent right Achilles or ankle reflex and a reduced left Achilles reflex; reduced vibration sense at the left ankle. At the time I examined him then I could not find any extensorplantar response. The Babinski was negative then. (R. 113)"

Dr. Nilges testifed that those findings were consistent with GBS. (R. 113)

Dr. Nilges found that Dr. Henry's report generally was consistent with the NINCDS criteria[2] in that George had progressive motor weakness, although the loss of reflexes was mislocated. (R. 148) While this loss of reflexes generally occurs in the lower extremities, there

are cases in which the loss of reflexes is found only in the upper extremities. (R. 122)

After his own examination of George, a review of all of the medical reports dating from August, 1976, until May 27, 1983, Dr. Nilges determined that George had permanent Guillian-Barre Syndrome. (R. 131)

GOVERMENT'S WITNESS

Dr. Harold L. Klawans, on September 18, 1981, examined George for the purpose of testifying. He concluded that George suffered from encephalomyelitis which was most likely secondary to the vaccination, plus peripheral neuropathy, which was unrelated. (S.R. 64,65) (R. 153) Dr. Klawans admitted that the diagnostic limits of GBS are still uncertain (R. 162); that there are a wide variety of cases; and that each case of GBS may have its own unique and surprising features. (R 163)

After hearing all the evidence the court[3] determined that the Plaintiff had not met her burden of proving it was "more likely than not" that George Karam had contracted GBS.

In reaching this decision, the Court stated that one of the NINCDS requirements for diagnosis of GBS (loss of deep tendon reflexes in the affected areas) did not appear during a neurological examination conducted two weeks after the onset of Mr. Karam's condition. Still not certain that this factor disposed of the case, the Court further considered:

(1) a complaint of numbness Mr. Karam made two years later as being inconsistent with GBS;

(2) the presence of a positive Babinski test which indicated central nervous system involvement; and

(3) Mr. Karam's loss of interest in his work subsequent to his illness as supporting Dr. Klawan's theory of a problem with the central nervous system.

ARGUMENT

I. THE FAILURE OF THE COURT TO FIND THAT GEORGE KARAM HAD CONTRACTED GUILLAIN-BARRE SYNDROME (GBS) WAS CLEARLY ERRONEOUS.

INTRODUCTION

Guillain-Barre Syndrome

Guillain-Barre Syndrome (at certain times referred to herein as "GBS"), a relatively rare disease affecting the nerves, is an evolving paralytic disease having a sub-acute course. Sub-acute refers to a course between acute (being short and relatively severe) and chronic. GBS is an illness with no known cause. GBS is not actually a specific disease, but a syndrome with a collection of signs and symptoms. Although the precise mechanism of GBS is unknown, GBS is generally thought to represent an aberrant immune response and it is generally thought that its characteristic pathological feature is an infiltration of lymphocytes (white blood cells) of the

peripheral nerve system and destruction of myelin (the fatty substance around the nerves). Myelin acts as an insulator, and it is an indispensable part of the nervous system; its loss is devastating.

A. The Trial Judge and the Court of Appeals Failed To Give The Treating Physican's Testimony Greater Weight Than Defendant's Hired Expert.

Plaintiff maintains that the evidence introduced in this cause conclusively demonstrates that the condition from which George Karam suffered as a result of the swine flu innoculation was, in fact, Guillain-Barre Syndrome (GBS). Four days after receiving the vaccine, George visited his personal physician complaining of symptoms (leg weakness) indicative of GBS. Following two weeks of observation and treatment at the hospital, Dr. Stambolis diagnosed his condition as GBS. (R. 32) This determination by Dr. Stambolis, after consultation with his neurological

specialists, was entered on George's medical records strictly with a view towards treatment and prognosis - not litigation. Furthermore, this early diagnosis of GBS was not a mere possibility because it was also the carefully considered opinion of other examining physicians. (R. 33,126,127,131)

Certainly, this evidence was entitled to greater weight than the theory of Dr. Klawans, a non-treating physician, who examined George once, and only at the defendant's request. In Dr. Klawans opinion, George did not suffer from GBS. Instead, Dr. Klawans offered an alternative diagnosis of his condition as that of post-vaccinal encephalomyleitis. (R.S. 50,52)

The Court erred by exclusively relying upon the testimony of this one physican, hired solely as an advocate without regard to medical treatment. Dr.

Klawan's single examination of George ocurred 5 years after the onset of the condition which immediately tends to cast doubt on his ability to make a reasonable diagnosis. This handicap being so obvious, his testimony essentially was confined to an interpretation of the notations, findings and opinions of other treating physicians. Still, in all of his testimony, Dr. Klawans was unable to identify any variance which would absolutely negate a diagnosis of GBS.

Where there is a difference of opinion between the treating physicians and a doctor hired for trial, this Court has repeatedly held that, "the opinions of a treating physican are entitled to substantially greater weight than those of a doctor who examined the plaintiff only once." Allen vs. Weinberger, 552 F.2d 781 (7 CA 1977); Carver v. Harris 634 F.2d 363 (7 CA 1980).

This logic was adopted in Clinton v. U.S. 530 F. Supp. 126 (E.D. Texas 1982) where the Court was faced with a situation identical to the one here. The treating physicans, although not neurologists, believed that the plaintiff had GBS. Their observations of the plaintiff stretched over a long period of time starting from the time that he recieved the vaccination. In contrast, the defendant's expert, who presented an alternative diagnosis, only examined the plaintiff once, four and one-half years after he had received the vaccine. The Court gave greater weight to the opinions of the treating physicans, and concluded that the plaintiff's condition was GBS. Similary, in Heyman vs. U.S., 506 F. Supp. 1145 (S.D. Fla. 1981), the Court chose to accept the GBS diagnosis of the plaintiff's expert "primiarily because he was (her) treating physican" and was more familiar with her medical history.

Based on the precedent of these cases, it was improper for the trial court to disregard the diagnosis, tests and opinion of George's treating doctors who determined that his illness was GBS. Instead, the Court substantially relied upon the testimony of the goverment's witness whose account generally leaves the distinct impression that he was more interested in establishing his own diagnosis (encephalomyelitis) than in negating that of the other physicians.

But most significant to this matter is the fact that the diagnosis of GBS rests primarily on clinical observations. (R. 86, 87 and R.S. 18) Increased familiarity with a patient (through repetitive examination and evaluation) facilitates accuracy of diagnosis, and here, George's treating physician, Dr. Stambolis, saw him frequently between 1976 and 1982, and was in direct contact

with the other attending specialists. Thus, he was able to interpret their data in conjunction with his personal observations and thereby stood in a unique position to evaluate George's condition.

B. The Evidence Is Overwhelming That Under The NINCDS Diagnostic Criteria, George Karam Developed Guillain-Barre Syndrome And No Other Illness.

At the outset it is essential that GBS be recognized for what it is, a syndrome, for which diagnosis depends primarily upon clinical observation. Both parties experts agreed that the actual diagnostic limits of this illness are still uncertain. (R. 96,162) As with any syndrome, it would be extremely rare to encounter the classic case displaying all the symptoms to a finely structured degree. To this end, plaintiff's neurologist testified that with the exception of the rapid onset of weakness, there are numerous variations to the

syndrome. (R. 90,92) Holding this thought to the side, plaintiff asserts that it was amply demonstrated, according to the defendant's own list of diagnostic criteria, that George Karam in fact contracted GBS.

A terse review of the evidence applicable to the NINCDS criteria[1] shows the mainfest weight of the evidence supported the plaintiff's position.

(A)

Under the criteria, two features are listed as requirements for diagnosis: progressive motor weakness of more than one limb and areflexia (loss of tendon jerks). Both of these symptoms were present in George Karam. In most instances the weakness is first noted in the legs and gradually ascends through the body. There is no doubt but that he had extensive weakness in both legs. Dr. Stambolis made numerous findings relevant

to this criteria (R. 33,50,55) Indeed, the Court had no difficulty in finding that this requirement had been met.

With regard to the areflexia, it was Dr. Stambolis' alarm at the lack of reflexes four days after the innoculation which prompted George's admittance into the hospital. (R.30) During Dr. Henry's examination (nine days later) George's reflexes were found to be absent in the arms but present in the legs. (R. 121)[2] This slight variance, however, does not divorce George's condition from GBS. Based on his own experience, Dr. Nilges recalled a case of GBS he treated where the patient had profound weakness in the legs, yet the reflexes were present. (R.122) More significantly, the nature of GBS is such that there may be intermittent exacerbations followed by recovery. (R. 130,131) Even Dr. Klawans admitted that progression often occurs in

a stepwise fashion. (R.173) Therefore, this accounts for the scattered tendon loss George exhibited in the early examinations, and is consistent with GBS. Furthermore, in subsequent testing, Drs. Stambolis, Glassenberg, Hasting, Nilges and also Dr. Klawans all found diminished or absent, reflexes in George's legs. (R. 60,113,126,127,175)

(B)

Other criteria under NINCDS are also listed as features which strongly support the diagnosis of GBS. These factors are listed in order of importance. It is noteworthy that George Karam exhibited the three highest ranking features, progression, relative symmetry, mild sensory symptoms and absence of fever.

(C)

Features casting doubt on the diagnosis are also specified in the NINCDS criteria, but all agreed that none were

present in George Karam (R. 106, 210) He also did not experience any of the features listed as ruling-out the diagnosis of GBS.

It is clear that when all these clinical observations and findings stand aligned with their respective NINCDS criteria, the composite of the evidence compels a finding of GBS.

An alternative diagnosis however, proposed by the Defendant's witness was that of encephalomylitis[3] most probably related to the vaccine. (R.S. 50, 52) It was first and only mentioned as a possible diagnosis by Dr. Haung, a consulting neurologist at the hospital (R. 50) According to Dr. Klawans, the criteria essential for a diagnosis of encephalomelitis vary as widely as those used to diagnosis GBS. (R.S. 60) Quite obviously this equally inexact syndrome was well-suited to serve the defendant's

position. In this regard, the witness was repeatedly willing to make substantial adjustments for those symptoms needed to support his diagnosis (e.g. fever disorientation) but would not accept any variation from the GBS features. (R.S. 60, 62)

Thus, the court's utter disregard of the enormity of the evidence demonstrating GBS and of the corroborative findings of the numerous examining physicians was clearly erroneous.

C. The Factors On Which The Court Rested Its Finding Either Disregard The NINCDS Criteria Or Have No Basis In The Evidence.

The court based its finding on the four factors discussed below, but those four factors, as will be shown, were either refuted, explained or unsupported by any evidence in the record.

(1) The loss of deep tendon reflexes in the legs did not appear during a

neurological examination conducted two weeks after the onset of George's illness.

In this regard, the court's reliance on the testing of George's reflexes at this point in time was clearly misplaced.[4] According to the NINCDS criteria, 90% of GBS cases reach their peak only by the fourth week. Furthermore, the remaining 10% still have not evolved by such time. Thus, it is obvious that the results of the premature testing to which the court here refers (two weeks after the onset of George's illness) were not sufficiently probative for purposes at hand. Significant to this matter, all subsequent examinations (by Drs. Stambolis, Hastings, Glassenberg, Nilges and Klawans) confirmed either absent or diminished reflexes in the affected areas. (R. 60, 113, 126, 127, 175).

(2) George Karam's complaint of numbness two years later was inconsistent with GBS.

(3) The presence of a positive Babinski reflex was troublesome because Dr. Klawans stated that it showed central nervous system involvement.

Finding this feature to be substantial in negating a diagnosis of GBS is contrary to the NINCDS criteria. Some central nervous system involvement appears likely to be present in GBS cases and is acceptable under the criteria. It is specifically listed among one of the variants in the features to be looked for in trying to diagnose GBS. Under this heading, the criteria goes on to explain:

> "Ordinarily the Guillain-Barre Syndrome is thought of as a disease of the peripheral nervous system. Evidence of central nervous system involvement is controversial. In occasional patients, such findings as severe ataxia, interpretable as cerebral in origin, dysarethria, extensor plantar[5] responses, and ill-defined sensory levels are

demonstrable, and these need not exclude the diagnosis if other features are typical."

(4) George Karam's own lack of activity was supportive of problems within the central nervous system.

In deciding that this feature (George's own lack of activity) negated the diagnosis of GBS, the court engaged in speculation and conjecture.[6] There was absolutely no medical testimony to show that such behavior by the victim of a neurological disorder is indicative of central nervous system disease. Certainly this could only be a medical determination, well beyond the scope of the trier of fact. To this end, the principle is well established that the findings of a court cannot be based on mere speculation. Neely v. St. Paul Fire and Marine Insurance Co., 584 F.2d 341 (9CA. 1978); Pittman v. Littlefield, 438 F.2d 659 (1CA. 1971).

Furthermore, George's lack of activity is consistent with a different interpretation which is not dependant upon medical evidence. Human experience tells us that losing the ability to walk and drive, particularly in our society and especially so late in years, would naturally effect a person's motivations. See Fraysier v. United States 566 F.Supp. 1085 (S.D.FlA. 1983) (where the court sympathetically observed that plaintiff's disabilities from GBS attacked his personality and left him disabled both from a physical and a mental standpoint because he was no longer able to be a contributing member of the family unit.)

SUMMARY

In deciding for the defendant on the basis of these four factors, the court obviously erred. As the evidence overwhelmingly demonstrates, the only proper diagnosis of George Karam's

condition was GBS. This was, in fact, the considered judgment of his treating physician and other consulting/evaluating doctors. Their opinions should not have been ignored in favor of the defendant's doctor, whose single sparse examination of George Karam occurred five (5) years after the onset of his illness.

Plaintiff is certain that, on this record, the reviewing court will be "left with a definite and firm conviction that a mistake has been committed." United States v. U.S. Gypsum Co., 333 U.S. 364, 395, 68 S.C t. 525, 92 L.E. 2d 746 (1948). Therefore, it is respectfully requested that this Honorable Court reverse the finding below and remand the cause for a determination on the amount of damages.

II. GEORGE KARAM'S POST-VACCINAL CONDITION FALLS UNDER THE UMBRELLA OF GBS, THUS, EQUITY FINDS THE GOVERNMENT LIABLE FOR HIS SUFFERING.

It was not the intent of the Swine Flu Act that a true victim should go uncompensated for a condition that arose directly from the innoculation. Here, there is no doubt that George Karam suffered substantial injuries as a proximate result of the government's immunization program. Even if this Court should determine that George's condition was not classic "criterial" GBS, it is nonetheless clear from all the evidence that his neurological disorder falls within the definition, classification and umbrella of GBS.

The medical literature indicates that the term Landry-Guillain-Barre Syndrome is an "all embracing phrase" meant to include a variety of neurological syndromes, including encephalomyelitis.

Leneman, The Guillain-Barre Syndrome, Archives of Internal Medicine, (1966) P.140. At trial, Dr. Nilges explained that one of the original names for GBS was "myelo" -- indicating nerve roots, radiculo -- indicating nerve roots, neuritis -- inflammation of the spinal cord, the nerve roots and the nerve themselves. (R.103).[7] This early terminology evidences that central nervous system involvement (of the type associated with encephalomyelitis) is consistent with the diagnosis of the GBS entity.

Whatever the pure designation of George Karam's condition may be, it certainly bears a close affinity with GBS (symptoms, ethiology nomenciature) even as this syndrome is restricted under the NINCDS criteria.

But, the NINCDS criteria utilized throughout this litigation cannot escape

scrutiny. These guidelines have been criticized for limiting and exluding the variability of signs and symptoms recognized by competent medical authorities.

In his review of the criteria, Dr. Charles Poser wrote:

> Central nervous system involvement and the degree to which it may occur and still allow for retaining the diagnosis of GBS continues to be controversial. Many authors have described clearcut central nervous system involvement in their cases... There has been ample demonstration of variable degrees of involvement of both central and peripheral nervous system after infections and vaccinations as well as in the experimentally induced disease... The peripheral nervous system involvement may be completely masked clinically by brain, cerebellar or spinal cord lesions and detectable only by electrodiagnostic studies...
>
> The state of the reflexes, the presence and persistence of bladder and bowel problems, even the presence of a distinct sensory level may reflect the existence of superimposed encephalitic or myelitic lesions. That such dissemination of lesions throughout the nervous system has been recognized as occurring when the clinical presentation is most suggestive of GBS led Baker (1943) to

> classify the syndrome into 5 clinical forms; abortive or mononeuritic polyneuritic, nyelitic, bulbar and cerebral. There is no evidence to suggest that swine flu vaccination would give rise to a "pure" GBS syndrome when other vaccinations, including those against influenza, result in a spectrum of illness ranging from encephalopathies to mononeuropathies... In fact, the well documented complications of the 1976 swine flu vaccination program demonstrated this same anatomical variability...

Poser, Criteria For The Diagnosis Of The Guilain-Barre Syndrome, A Critique Of NINCDS Guidelines. Journal of Neurological Sciences, Vol 52 at 193-194 (1981) (citations omitted) (Emphasis added).

Notably, in Fraysier v. United States, 566 F.Supp. 1085 (S.D.Fla. 1983) the doctors responsible for the NINCDS* guidelines (appearing through the use of video-taped depositions) acknowledged the imperfections of the cirteria and stated that error should be made on the side of the patients and not the government when symptoms appear between

the third day and sixth week after innoculation. In this case, George Karam reported symptoms of weakness in the legs four days after he received the flu shot. Unquestionably, this is the major feature for the diagnosis of GBS. Furthermore, most of George's symptoms were representative of the disorder even as it is limited by the cirteria. Thus it would be inequitable to further burden the plaintiff with a standard whose own authors have admitted as being faulty.

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* It is of interest to note that the surveillance conducted by the Center for Disease Control which established a causal relationship between the Swine Flu vaccine and Guillain-Barre Syndrome was completed prior to the development of the NINCDS criteria. Retailliau, Illness After Influenza Vaccination Reported Through a Nationwide Surveillance System, General Review, A.J. Epidemiology, Vol. III, No. 3 (1980).

The standards which were utilized to define and diagnose the disorder during that time are unknown. It is thus likely that the reported rash of GBS case (which pinpointed this

particular condition for special recognition by then Secretary of Health, Education and Welfare, Joseph A. Califano) did not themselves measure up to strictness suggested by the NINCDS criteria. (See Statement of Secretary Califano, June 20, 1978)

In this regard, one medical authority observed that GBS is not reportable disease in the United States as required by State Health boards which suggests that nurmerous cases of GBS have been misreported or mislabeled. Morgenstern and White, Guillain-Barre Syndrome Following Vaccination, Lawyers Medical Journal. Vol 9 page 465 (1981).

Finally, the essential purpose of the Swine Flu Act was to free vaccine manufacturers from liability and thereby hasten the distribution for the vaccine. By assuming liability in this manner Congress evidenced the intent to compensate all valid claims which arose from the immunization program. See, remarks of Congressman Paul G. Rogers of Florida on the position of the government. ("We have asked the drug companies to produce this vaccine. We have told them how to do it. We gave

them the specification because we are the only buyers, the Government of the United States. This is not the usual process of going out and selling. But if someone is hurt, we think people ought to have a remedy.") 122 Cong. Rec. 26796 (August 10, 1976) (Emphasis added)

It is clear that when Congress took the unprecedented action of assuming primary liability it fully intended that true victims of the Swine Flu vaccine be compensated. It is also clear on the facts of this case that plaintiff presents a valid claim. George Karam was in no way responsible for his suffering. He incurred substantial injuries as a proximate result of the government's immunization program. Certainly, the spirit of the Swine Flu Act suggests a remedy.

The decision of the Court of Appeals in its only citation of authority Yorger

Pittsburg Corning Corp., 733 F.2d 1215, 1220 (7th Cir. 1976) ruled that this argument had been waived. In Yorger, the court found there had been no waiver. Further the court qualified the waiver argument and precluded its application "where the obvious result would be a plain miscarriage of justice." Surprisingly it was the defendant's witness who diagnosed Karam's condition as encephalomyelitis from the Swine Flu innoculation. Therefore, in a review of a mandatory bench trial, the court should not have considered this argument under any circumstances to be waived but rather prevented a clear miscarriage of justice.

The doctors responsible for the NINCDS guidelines acknowledged the criteria are imperfect. Congress' sole purpose for the Swine Flu Act was to free vaccine manufacturers from liability, not to limit claims. Karam belonged to the class intended to be protected.

In sum, the better view as suggested by the medical literature, by the authors of the criteria used at trial, and by the spirit of the Swine Flu Act requires that plaintiff be justly compensated for the injuries George Karam suffered as a result of the Swine Flu innoculation.

CONCLUSION

For the above-mentioned reasons this court should find that George Karam had Guillain-Barre Syndrome and thus remand this case to determine the amount of damages.

Respectfully submitted,

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APPENDICES

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FOOTNOTES

Statement of Facts

1/ A syndrome is defined as a collection of signs and symptoms which occur together as a group and usually indicate a particular disease state. A syndrome becomes a disease when a specific etiology (cause) or pathology (microscopic examination) is established.

2/ The Neurological and Communicative Disorders and Stroke (NINCDS) committee set out to characterize GBS, clearly enough for field studies. In doing so many cases were excluded for fear of contaminating the test group. The criteria set out by NINCDS were not promulgated until 1978, two years after swine flu vaccination caused a number of reported cases of GBS. The complete study is found in the Appendix. Also included in the appendix is the historical background of the Swine Flu Program.

3/ The Trial Court's finding is in the Appendix attached hereto.

Argument

1/ The "criteria" are actually far removed from being that, but rather are only tools to aid in diagnosis. This is obvious because they provide no clues as to the possible skewing of symptoms in the presence of other pre-existing maladies e.g. George Karams' diabetic condition. See Fraysier v. United States, 566 F.Supp. 1085,1089 (S.D.Fla. 1983) where the doctors responsible for criteria stressed that, account must be taken of any underlying or collateral

diseases which might distort the symptoms.

2/ The symptoms of GBS generally peak within four weeks of onset.

3/ Encephalomyelitis is defined as a disorder of the central nervous system in which there are multiple areas of inflammation within the brain and spinal cord. The Attorneys' Dictionary of Medicine, Schmidt (1978).

4/ The time of examination for deep tendon reflexes is obviously crucial. See, Clinton v. United States, 530 F.Supp. 126 (E.D Texas, 1982) where the court allowed similar deviation by considering the plaintiff may have regained his reflexes before he was tested.

5/ A synonym for "Babinski" reflex. The Attorneys' Dictionary of Medicine, Schmidt (1978) defines Babinski reflex as the stimulator of the sole of the foot which normally causes all the toes to flex or bend down. But, in certain diseases of the brain and spinal cord, the big toe will extend or bend upward.

6/ Speculation has been described as the art of theorizing about a matter as to which evidence is not sufficient for certain knowledge. LeGrand v. U-Drive-It Co., 247 S.W.2d 706,712 (Mo. 1952) cited in Jaramillo v. United States, 357 F.Supp. 172 (S.D.N.Y. 1973)

7/ GBS has commonly encountered various other designations including: idiopathic polyneuritis, acute febrile polyneuritis, infective polyneuritis, postinfectious polyneuritis, acute toxic polyneuritis, acute polyneuritis with

facial diplegia, acute infectious neuronitis, polyneuronitis, mononeuronitis, radiculoneuritis, polyradiculoneuritis, myeloradiculoneuritis, myeloradiculitis, Guillain-Barre syndrome, Guillain-Barre-Strohl syndrome, and Landry-Guillain-Barre syndrome.

History

In early January, 1976, a minor outbreak of a new strain of influenza was cultured from soldiers at Fort Dix, New Jersey. The new strain -- called swine flu because it is also found in pigs -- produced an antibody in infected persons identical to that produced in people who developed influenza during a world-wide pandemic in 1918-1919. That pandemic resulted in approximately 450,000 deaths in the United States and between 20 and 30 million deaths worldwide. Because it was impossible to determine if this new strain was the same as the 1918 influenza, there was alarm among health officials in the United States.

Upon the recommendation of Department of Health, Education and Welfare officers and numberous medical experts, then President Gerald R. Ford proposed a national immunization program to Congress

in March, 1976. On April 15, 1976, President Ford signed a bill appropriating $135 million for the immediate development of such a program. The program was to achieve the unprecedented goal of immunizing every American without regard to age or existing physical maladies.

By early June, 1976 that goal was in serious trouble. Perhaps fostered by earlier cases imposing liability on vaccine manufacturers during the polio immunizations in the 1960's, the private insurance carriers of the swine flu vaccine manufacturers either cancelled or greatly limited their liability coverage. The manufacturers in turn refused to sell their vaccine unless the federal government provided some form of liability protection. Again at the urging of President Ford and after several weeks of Congressional hearings,

legislation was introduced in Congress on August 2, 1976 creating the National Swine Flu Immunization Program. Among other things, the legislation relieved the caccine manufacturers and all otherprogram participants from primary liability and created an exclusive remedy against the United States for any injuries resulting from the immunization program.

With unparalleled haste, the bill came before the Senate on August 10, 1976, without hearings or a committee report, and was passed in amended form. 122 Cong. Rec. 26639 (August 10, 1976). The bill was sent to the House of Representatives, and even though many members had neither seen nor read the legislation, was expeditiously passed that same day. Id at 26817. President Ford signed the National Swine Flu Immunization Program of 1976 into law on August 12, 1976.

Between October 1, 1976 and December 10, 1976 over 40 million Americans or one-third of the adult population of the United States were vaccinated. This made the Swine Flu Act the largest vaccination program in history. In conjunction with the Swine Flu Act, the Department of Health, Education and Welfare conducted a surveillance program to evaluate illness temporally associated with influenza vaccination. By December 2, 1976, seven cases of GBS in two clusters had been reported. On December 16, 1976, based on data from four test States, the immunization program was suspended.[1]

1/This history is taken from Unthank v United States, 533 F.Supp. 703 (N.D. Utah 1982). It represents a clear and concise review of the situation and leads to a better understanding of this matter.

UNITED STATES COURT OF APPEALS
For the Seventh Circuit
Chicago, Illinois 60604
July 31, 1985

Hon. WALTER J. CUMMINGS, Chief Judge
Hon. RICHARD D. CUDAHY, Circuit Judge
Hon. WILLIAM P. GRAY, Sr. District Judge*

PAULETTE P. KARAM, Special Administratrix of the Estate of George L. Karam, Deceased, Plaintiff-Appellant,	)Appeal from the)United States)District Court)for the Northern)District of)Illinois, Eastern)Division.
No. 84-1311	)
vs.	)No. 80 C 156))
UNITED STATES OF AMERICA, Defendant-Appellee.	)))Paul E. Plunkett,)Judge.

O R D E R

This is an action for personal injury and damages under the National Swine Flu Immunization Program Act of 1976, 42 U.S.C. § 2476, and the Federal Tort Claims Act, 28 U.S.C. § 1346(b) et seq. Plaintiff appeals from the trial court's ruling that the United States was not

* Honorable William P. Gray, Senior District Judge for the Central District of California, is sitting by designation.

liable for her husband's illness following his receipt of a swine flu immunization. We affirm.

I.

Plaintiff's decedent, George Karam, was self-employed as an insurance salesman. Prior to December 3, 1976, Mr. Karam had various medical problems, including diabetes and peripheral neuropathy, but was generally productive and energetic. On that date, Mr. Karam received a bivalent vaccine by innoculation (the "swine flu vaccination") from his personal physician, Dr. Stambolis. On or about December 7, 1976, he developed serious problems with his legs which caused him to see Dr. Stambolis, On Dr. Stambolis' advice, he was hospitalized on December 8, 1976. In the years following the vaccination, Mr. Karam had various medical problems (some of which were stipulated to be unrelated to the

vaccination). His medical complaints included difficulty in walking and numbness in both legs. The parties agreed that Mr. Karam suffered from a neurological disorder, but disagreed on its diagnosis and cause.

In a pre-trial order the parties agreed to a statement of several contested issues of fact and law; the only one of these relevant to this appeal is whether Mr. Karam developed Guillain-Barre Syndrome ("GBS") following receipt of the swine flu vaccination. Plaintiff maintains that Mr. Karam contracted GBS as a direct result of the swine flu vaccination he received on December 3, 1976. Although the United States agreed that swine-flu vaccinations can cause GBS, it contended that Mr. Karam suffered from an episode of encephalomyelitis after the vaccination, and that his subsequent medical problems were not

caused by that vaccination. Thus, the dispositive issue before the court was whether Mr. Karam had GBS following the swine flu vaccination in 1976. If he did, the government conceded causation and liability for damages caused by that syndrome; if he did not, the plaintiff agreed that the United States was not liable to her.

II.

After a mandatory bench trial, the trial court concluded that plaintiff had not sustained her burden of proving that Mr. Karam's medical difficulties were attributable to GBS. Plaintiff's primary argument on appeal is that the finding that Mr. Karam did not have GBS is clearly erroneous. Initially, plaintiff contends that the trial court paid insufficient attention to the testimony of Mr. Karam's treating physician, Dr. Stambolis, and indeed, that it should

have given Dr. Stambolis' testimony greater weight than that of Dr. Klawans, defendant's expert witness.

About two weeks after Mr. Karam was admitted to the hospital, Dr. Stambolis diagnosed Mr. Karam's condition as GBS. Since Dr. Stambolis was quite familiar with Mr. Karam's medical history, since he observed Mr. Karam's condition beginning shortly after the vaccination and since he consulted with other attending physicians during Mr. Karam's hospital stay, plaintiff argues his diagnosis should have been far more persuasive than that of Dr. Klawans. As the government points out, however, plaintiff did not offer Dr. Stambolis as an expert on GBS, and in fact in clsing argument plaintiff's attorney specifically stated that the purpose of Dr. Stambolis' testimony was only to show that the onset of many of Mr. Karam's

physical problems occurred shortly after the shot. Moreover, even if plaintiff had argued below that Dr. Stambolis' diagnosis was entitled to substantial weight, we would not find it erroneous for the trial court to have given his opinion little or no credence. No blanket rule exists that a treating physician's opinion should always be given greater deference than that of another doctor, particularly where, as in this case, the treating physician was not a specialist in neurology, and had never before diagnosed or treated a case of GBS, while Dr. Klawans was an expert in such matter.

Plaintiff also makes various specific arguments intended to demonstrate that Mr. Karam did suffer from GBS. Both parties rely heavily on an article entitled "Diagnostic Considerations in Guillain-Barre Syndrome," by Dr. Arthur

K. Asbury, Ann. Neurol. 9 (Supp.) 1-5, 1981, which includes the full text of a report by the National Institute of Neurological and Communicative Disorders and stroke characterizing the GBS disorder (hereafter referred to as the 'NINCDS criteria"). Two features are listed in the NINCDS criteria as requirements for diagnosis of GBS: progressive motor weakness of more than one limb, and areflexia (loss of tendon jerks). The trial court found that the first requirement had been demonstrated, but that there was insufficient evidence of areflexia.

The evidence about loss of tendon reflexes was disputed. Dr. Stambolis testified that Mr. Karam's leg reflexes were diminished at the initial examination on December 7, 1976, but he admitted that he did not record any observation of diminished reflexes until March 28, 1977.

An examination two weeks after the onset of Mr. Karam's illness disclosed no loss of reflexes until March 28, 1977. An examination two weeks after the onset of Mr. Karam's illness disclosed no loss of reflexes in the legs. The references in the record cited by plaintiff indicate only diminished reflexes in the legs and feet, which Dr. Klawans testified was insufficient to demonstrate the complete loss of deep tendon jerks typically associated with GBS. Although some other physicians involved with the case found diminished reflexes in Mr. Karam's arms, Dr. Klawans testified that the loss of deep tendon reflexes must be in the affected areas (in this case, the legs) for a diagnosis of GBS to be correct. Plaintiff's expert, Dr. Nilges, acknowledged that typically in GBS, tendon reflexes are abolished in the affected areas. Under these

circumstances, we cannot say that the trial court's finding that Mr. Karam did not have areflexia in the affected areas was clearly erroneous.

Although the trial court might well have been justified in relying solely on the lack of areflexia in the affected areas to support his finding that Mr. Karam did not have GBS, this was not the only factor it considered. Instead, the court noted three other factors which Dr. Klawans had testified all weighed against the presence of GBS: numbness, a positive Babinski test and drowsiness and lethargy. Plaintiff argues that according to the NINCDS criteria as well as some of the expert testimony, none of these factors need rule out a diagnosis of GBS and some or all may be consistent with it. Moreover, plaintiff stresses that various other criteria that are supportive of a diagnosis of GBS were

demonstrably present in this case. Acceptance of these propositions, however, does not lead to the conclusion that the trial court's finding that Mr. Karam did not have GBS was clearly erroneous. As in many cases, each party brought in an expert and those experts disagreed about the existence and significance of various relevant matters under observaiton. Each party points to facts and opinions that aid its own case and detract from its opponent's. Especially in a case such as this one which involves myriad technical and sometimes controversial issues, the court must necessarily give deference to the expert whom it believes provides the most credible and helpful information. In this case, the trial court found that the conclusions of government's expert, Dr. Klawans, were most consistent with the medically-recognized NINCDS standards and

the evidence in the case. Our review of the record and briefs persuades us that the evidence supports the conclusion that Mr. Karam did not have GBS; certainly the trial court's finding to that effect is not clearly erroneous.

III.

Finally, plaintiff appeals to equity in arguing that even if George Karam's post-vaccinal condition was not "classic" GBS, it falls under the "GBS umbrella," or in other words is sufficiently closely related to GBS that plaintiff should be compensated for the condition. Plaintiff cites an array of medical literature for the proposition that GBS may encompass a wide variety of interrelated or similar syndromes, including encephalomyelitis, and contends that Congress' intent in enacting the Swine Flu Act surely was to provide compensation for all valid claims of injuries resulting from swine flu

vaccinations. Regardless of the potential merit of such contentions, the short answer is that they were not argued, much less proven, at trial. It is axiomatic that n issue not presented below cannot be raised for the first time on appeal and form the basis for reversal. Yorger v. Pittsburg Corning Corp., 733 F.2d 1215, 1220 (7th Cir. 1976).

The parties clearly agreed in the pre-trial order that the determinative issue was whether Mr. Karam had Guillain-Barre Syndrome, and there is nothing in the record to indicate that the scope of the issue was expanded in any way at trial. Indeed, the pretrial order explicitly states that the defendant's theory was that Mr. Karam suffered from encephalomyelitis; at various points plaintiff disputed such a conclusion and certainly never argued that it would

support a finding of liability. Issues that would be relevant to plaintiff's "umbrella" theory, such as causation and congressional intent, were never explored below. As sympathetic as we are to the plaintiff's case, we cannot impose liability on the government where its responsibility for the plaintiff's medical problems was not established. Therefore the district court's order is AFFIRMED.

IN THE UNITED STATES DISTRICT COURT
NORTHERN DISTRICT OF ILLINOIS
EASTERN DIVISION

PAULETTE P. KARAM, etc.,	)	
Plaintiff,	)	
vs.	)	No. 80 C 156
UNITED STATES OF AMERICA,	)	Chicago, Illinois February 9th, 1984 11:00 o'clock, a.m.
Defendant.	)	

EXTRACT OF PROCEEDINGS
BEFORE HONORABLE PAUL E. PLUNKETT

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* * * *

THE COURT: I think I begin by saying I would like to compliment the lawyers on both sides because the question of this Guillain-Barre syundrome is one which I had never heard of before and I think by the time the very able lawyers in this case got through presenting it at least I became comfortable with dealing with the terms and the problems contained in ti.

The sole question presented, as the Court understands it, is whether Mr.

Karam had Guillain-Barre syndrome, because the government concedes that if he did the causal nexus between the flu vaccination and the syndrome itself is a given.

The Court recognizes the plaintiff bears the burden of proving it is more likely than not that Mr. Karam had the Guillain-Barre syndrome. The Court accepts the propositions contained in the NINCDS study and the features required for diagnosis being progressive motor weakness in more than one limb and areflexia, which is the loss of tendon jerks. The Court recognizes that medical science, lik law, learns as it goes along, and that these are not written in stone but are the best available standards that the medical profession can give us in deciding the question.

I find that Mr. Karam did meet the requirement of, No. 1, the feature

required for diagnosis that he have progressive motor weakness of more than one limb, and it certainly did range from minimal to total. It fell somewhere in the middle.

The second requirement, that there be areflexia, of loss of tendon jerks, does not seem to have been met in this case because two doctors, one a neurosurgeon and one a neurologist, found two weeks after the onset of Mr. Karam's problems that he had basically normal deep tendon reflexes in the affected areas, namely, the legs.

I wasn't sure that this necessarily disposed of the case so I went a little bit further and considered the following things: There is a finding in Mr. Karam that seems to come in about two years later of numbness, which also seems inconsistent with this GBS syndrome. Thre is a findiong of a positive

Babinski test which Dr. Klawans tells me, and I think it is uncontroverted, strongly supports, or, as he puts it, absolutely shows a central nervous system involvement, because the brain no longer blocks out or acts as a damper on the reflex action.

I also note that Mr. Karam's work history is somewhat interesting because, as Mr. McCambridge told me, he was a workaholic, and it seems to me that he basically just lost interest in his work after the onset of his problems. That is consistent with the medical notations of drowsiness and lethargy, and that is all, at least as Dr. Klawans tells me, supportive of a problem in the central nervous system rather than peripheral system.

In short, I think Mr. Karam's own lack of activity can be found to support Dr. Klawans' view that the central nervous

system was involved rather than the peripheral system.

Accordingly, the Court finds -- and I have to say I do so somewhat reluctantly because I think the Court, too, has sympathy for Mrs. Karam and for Mr. Karam, who had a vry unpleasant seven years of life, but with great reluctance I find that the plaintiff has not sustained her burden of proving the existence of the GBS and I find for the defendant.

I would like the plaintiff to let my clerk know at some appropriate time whether there is going to be an appeal because, if there is, I reserve the right to take this oral opinion and make a written opinion from it.

NO. 85-

IN THE
SUPREME COURT OF THE UNITED STATES

PAULETTE KARAM, Special Administratix
of the Estate of George L. Karam,
Deceased,

Plaintiff-Petitioner

v.

UNITED STATES OF AMERICA,

Defendant-Respondent

NOTICE OF FILING

TO: Anton Valukas, U.S. Attorney
219 South Dearborn Street
Chicago, Illinois 60603

Office of the Solicitor General
U.S. Department of Justice
Main Justice Building
Washington, D.C. 20530

PLEASE TAKE NOTICE that on the 13th day of November, 1985, I filed with the Clerk of the United States Supreme Court for presentation to the Judges the Petition For Writ of Certiorari on behalf of Plaintiff-Petitioner, PAULETTE KARAM, et al.

AMBROSE & CUSHING, P.C.
Attorneys for Plaintiff-Petitoiner
7 South Dearborn St.
Chicago, Illinois 60603
(312) 726-1470

STATE OF ILLINOIS)
) SS.:
COUNTY OF C O O K)

AFFIDAVIT OF MAILING

I, JOHN C. AMBROSE, after first being duly sworn upon oath depose and say:

1. That I am the Attorney of Record for the Plaintiff-Petitioner, PAULETTE KARAM, Special Administratrix of the Estate of George Karam, Deceased, in the Petition for Writ of Certiorari;

2. That pursuant to the Rules of Practice of the Supreme Court of the United States, I certify the forty-five (45) copies of the Petition For Writ of Certiorari and Appendix were mailed to the Clerk of the United States Supreme Court on November 13, 1985 to be filed as of October 28, 1985;

3. That pursuant to the Rules of Practice of the Supreme Court of the United States, I certify that three (3) copies of the Petition For Writ of Certiorari and Appendix were mailed to:

(a) Anton Valukas, U.S. Attorney
219 South Dearborn Street
Chicago, Illinois 60603

(b) Office of the Solicitor General
U.S. Department of Justice
Main Justice Building
Washington, D.C. 20530

on October 28, 1985 by placing the same in an envelope with the above-mentioned names and addresses and depositing said envelopes in the U.S. Mail in Chicago, Illinois on November 13, 1985.

JOHN C. AMBROSE

SUBSCRIBED and SWORN to
before me this 13th day
of November, 1985.

NOTARY PUBLIC